4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0766]

Hospira, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on May 20, 2022. The document announced the withdrawal of approval (as of June 21, 2022) of 21 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDAs after receiving withdrawal requests from Bionpharma Inc., 600 Alexander Rd., Suite 2-4B, Princeton, NJ 08540: ANDA 065301, Cefadroxil Tablets, Equivalent to (EQ) 1 gram (g) base; ANDA 065307, Cefadroxil Oral Suspension, EQ 250 milligrams (mg) base/5 milliliters (mL) and EQ 500 mg base/5 mL; ANDA 065309, Cefadroxil Capsules, EQ 500 mg base; ANDA 065326, Cephalexin Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL; from Sunny Pharmtech Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027: ANDA 203581, Glyburide Tablets, 1.25 mg, 2.5 mg, and 5 mg; and from Unicorn Pharmaceuticals, 5 Links Circle, Durham, NC, 27707: ANDA 204137, Omeprazole and Sodium Bicarbonate Capsules, 20 mg; 1.1 g. Before FDA withdrew the approval of these ANDAs, Bionpharma Inc., Sunny Pharmtech Inc., and Unicorn Pharmaceuticals informed FDA that they did not want the approval of the ANDAs withdrawn. Because Bionpharma Inc. timely requested that approval of ANDAs 065301, 065307, 065309, and 065326 not be withdrawn, the approvals are still in effect. Because Sunny Pharmtech Inc. timely requested that ANDA 203581 not be withdrawn, the approval is still in

effect. Because Unicorn Pharmaceuticals timely requested that ANDA 204137 not be withdrawn, the approval is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, May 20, 2022 (87 FR 30962), in FR Doc. 2022-10924, the following correction is made:

On page 30963, in the table, the entries for ANDAs 065301, 065307, 065309, 065326, 203581, and 204137 are removed.

Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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